Exhibit #1 510(k) Summary

APR 1 4 2011

Disposable Endometrial Suction Curette
As required by 21 CFR 807.92(k)

The assigned 510(k) Number is: K102847

1. Date Prepared: September 27, 2010

2. Sponsor Information

Jiangsu Suyun Medical Materials Co., Ltd
No.18, Jinqiao Road, Dapu Industrial Park,
Lianyungang Economic Development Zone,
Lianyungang, Jiangsu, 222000, China
Establishment Registration Number: 9680254

Contact Person: Mr. Guangning Xu, Quality Manager
Tel: +86-0518-85608151
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E-Mail: quality@suyunmedical.com

3. Submission Correspondent

Ms. Diana Hong, Mr. Lee Fu
Mid-Link Consulting Co., Ltd
P.O. BOX 237-023, Shanghai, 200237, China
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

4. Proposed Device

Device Trade Name: Disposable Endometrial Suction Curette
Model: Type A and Type B
Device Classification Name: Curette, Suction, Endometrial (And Accessories)
Product Code: HHK
Regulation Number: 21 CFR 884.1175
Device Class: II
Review Panel: Obstetrics/Gynecology

Intended Use:

The Disposable Endometrial Suction Curette is indicated for obtaining endometrial tissue samples by vacuum suction for endometrial histopathology examination.

The specimens obtained are then used for the following:

- Endometrial cancer detection
- Determine response to estrogen replacement therapy
- Detection of pathology resulting in:
  - Infertility
  - menstrual disorders
  - abnormal or dysfunctional uterine bleeding
  - postmenopausal bleeding
- endometrial dating

5. Predicate Device Identification:

510(k) Number: K974819
Trade/Proprietary Name: SelectCells™Mini
Submitter: Select Medical Systems, Inc
Classification Name: Curette, Suction, Endometrial (And Accessories)

Intended Use:
The SelectCells™Mini is s single use, sterile, disposable endometrial sampling device designed to be used for obtaining a histologic biopsy of the uterine mucosal lining or specimen of the uterine menstrual content.
The specimen obtained is then used for the following:

(i) evaluation of infertility conditions, menstrual disorders, postmenopausal bleeding, abnormal cytology suspected of being of endometrial origin, hormonal replacement therapy;
(ii) detection of endometrial carcinoma;
(iii) diagnosis of luteal defect;
(iv) endometrial dating and,
(v) microscopic examination.

6. Device Description:

The proposed device is single-use, sterile disposable endometrial suction curette, which is intended to obtain endometrial tissue samples by vacuum suction mainly for endometrial histopathology examination and cytological examination or clinical examination in Gynaecological examination.

Disposable Endometrial Suction Curette, including Type A and Type B, consists of a rod, barrel and sealing ring. The rod is used to generate negative pressure to draw the sample (fluid or

mucous) into the barrel. The barrel is used to contain the drawn samples. The sealing ring ensures that the handle can be assembled closed with the barrel for keeping certain negative pressure.

7. Test Conclusion

There is no published standards for these particular types of products, and as such tests have been developed which are considered sufficient to ensure the efficacy and safety of the device for its intended use. Such tests include – Visual; Dimensional; and Functional.

8. Substantially Equivalent Conclusion

The proposed device, Disposable Endometrial Suction Curette, has been tested and compared to predicate device, and it is determined to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Jiangsu Suyun Medical Materials Co., Ltd.
c/o Ms. Diana Hong
Submission Correspondent
Mid-Link Consulting Co., Ltd.
P.O. Box 237-023
SHANGHAI 200237
CHINA

APR 14 2011

Re: K102847
Trade Name: Disposable Endometrial Suction Curette
Regulation Number: 21 CFR §884.1175
Regulation Name: Endometrial suction curette and accessories
Regulatory Class: II
Product Code: HHK
Dated: March 14, 2011
Received: March 16, 2011

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit #2 Indication for Use Form

510(k) Number: K102847
Device Name: Disposable Endometrial Suction Curette

Indications for Use:

The Disposable Endometrial Suction Curette is indicated for obtaining endometrial tissue samples by vacuum suction for endometrial histopathology examination.

The specimens obtained are then used for the following:

- Endometrial cancer detection
- Determine response to estrogen replacement therapy
- Detection of pathology resulting in:
  - Infertility
  - menstrual disorders
  - abnormal or dysfunctional uterine bleeding
  - postmenopausal bleeding
- Endometrial dating

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102847